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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/776,350	04/18/1997	ALASDAIR R. MACLEAN	117-231	1818

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/14/2003

47

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/776,350

Applicant(s)
Maclean et al

Examiner
Unger

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 16, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-45, 47, 51, and 59 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-45, 47, 51, and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1. The Amendment filed September 15, 2003 (Paper No. 39) in response to the Office Action of August 15, 2003 (Paper No. 38) is acknowledged and has been entered. New claim 59 has been added. Claims 43-45, 47, 51, 59 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are maintained:

Claim Rejections - 35 USC § 103

4. Claims 43-45, 47, 51 remain rejected under 35 USC 103, and newly added claim 59 is rejected under 35 USC 103, for the reasons previously set forth in Paper No. 34, Section 4, pages 1-2, Paper No. 31, Section 7, pages 4-6.

It is noted for Applicant's convenience that, for examination purposes, the phrase "consists essentially of" in newly added claim 59 is interpreted as open language, equivalent, for example to the term "comprising".

Applicant reiterates arguments drawn to a non-functional ribonucleotide reductase gene. The arguments have previously been considered and have not been found persuasive for the reasons of record.

Applicant requests clarification because the Examiner appears to be asserting that there are some other genes outside of the entire genome of HSV-1 which may include the ribonucleotide reductase gene of the cited patent. Examiner apologizes for any inconvenience due to a misreading of part of the prior art patent.

Applicant argues that the closed language of the claim excludes the non-functional ribonucleotide reductase gene required by the prior art. The argument

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has been considered but has not been found persuasive because the language is not closed for the reasons of record. Further, the specification specifically contemplates mutations in the virus other than those in the gamma 34.5 gene and there is nothing in the language of the claims that excludes any additional mutations or alterations of the viral genome. (see pages 6-7 of the specification).

Applicant argues that at best R3616 may be effective when tested in an intracranial glioma model which is not the same as the instantly claimed invention. The argument has been considered but has not been found persuasive because Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that the '096 patent concerns only an HSV-1 mutated in two genes. The Examiner appears to repeatedly equate the capacity of a virus to infect tumor cells with treatment of tumor cells, however the capacity to infect does not necessarily equate with or make obvious a capacity to treat since it is well known that a virus may be able to infect cells but nevertheless be unable to replicate in or lyse cells. HSV 1716 can infect non-tumour bearing mouse brain but not replicate in normal mouse brain cells and none of the cited art teach or suggest that mutant

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HSV can infect metastatic tumour cells. The argument has been considered but has not been found persuasive because R3616 clearly is an neuro-avirulent construct, it clearly replicates in replicating tumor cells and for the reasons previously set forth, the combined references make obvious the claimed invention.

Applicant argues that HSV-1 infects a melanoma cell line which is capable of metastasizing but does not teach or suggest that HSV-1 infects metastatic melanoma *in situ*. The argument has been considered but has not been found persuasive because once again, Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Given the teachings of the combined references, the invention is obvious for the reasons of record.

Applicant points to Randazzo et al and argues that B-16 cells could be infected by HSV but were resistant to lysis by HSV-1 isolates including wild-type and gamma 34.5 mutant HSV-1. The argument has been noted but cannot be considered because it does not appear that the reference has been submitted.

Applicant reiterates arguments drawn individually to the '096 patent. The arguments have been considered but have not been found persuasive for the reasons

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of record. Applicant's arguments have not been found persuasive and the rejection is maintained.

Objection to the Amendment of the Specification

5. Applicant argues that lines 3-10 of Paper No. 4 state that the contents of WO92/13943 are incorporated by reference and Examiner is asked to reconsider the new matter rejection drawn to the incorporation by reference in the Paper submitted on January 22, 2001. The request has been considered but has not been found persuasive, the rules regarding incorporation by reference are very clear. Although WO 92/13943 was incorporated by reference in the instant application, this incorporation does not support the incorporation of US Patent No. 6,040,169 for the reasons of record. Applicant is required to cancel the new matter in response to this Office Action.

6. All other objections and rejections recited in Paper No. 34 are hereby withdrawn.

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar
Primary Patent Examiner
October 10, 2003